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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,937	04/14/2000	Michael B Chancellor	28682-501-CIP	9119

7590 07/25/2005

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/549,937	Applicant(s) CHANCELLOR ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 107, 110-112, 114, 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 190, 193-197, 199-201, 204-206, 209-211, 216-229 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 220 and 222 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 107, 110-112, 114, 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 190, 193-197, 199-201, 204-206, 209-211, 216-219, 221, and 223-229.

Art Unit: 1635

DETAILED ACTION

Non-Final Rejection

Claims 107, 110-112, 114, 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 190, 193-197, 199-201, 204-206, 209-211, and 216-229 are pending.

Applicant's traversal, the cancellation of claims 1-106, 108, 109, 113, 115-153, 155, 156, 162, 164, 165, 171, 172, 179, 184, 186-189, 191, 192, 198, 202, 203, 207, 208, and 212-215, the amendment to claims and the addition of claims 218-229 in paper filed on 3/17/05 is acknowledged and considered by the examiner.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/05 has been entered.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-

Art Unit: 1635

part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The status of US application 09/302,896 listed in the cross reference is incorrect because the US application '896 is now US Patent No. 6,866,842.

Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: the status (patented US Patent No. 6,866,842) of US application 09/302,896 listed on page 14, line 30, page 15, lines 2 and 7, page 28, line 31, page 29, line 17 needs updating.

Claim Objections

Claims 220 and 222 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107-112, 114, 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 216-218 and 223-229 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written

Art Unit: 1635

description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New matter rejection

The limitation '(b) replating non-adherent cells from step (a) in a second collagen-coated container' in amended claims 107, 154, 163, 170, 178, 216 and claims dependent therefrom is not supported by the as-filed specification. The limitation is broader than the previous limitation for step (b) in the claims. See *In re Wertheim* 541 F. 2d 257, 191 USPQ (CCPA 1976). There appears to be no written description of the claim limitation "(b) replating non-adherent cells from step (a) in a second collagen-coated container" in the application as filed. See MPEP § 2163.06. Applicant asserts that support for the limitation is found on page 29, lines 14-23 of the instant specification. Page 29 is directed to pre-plating cells in collagen-coated flask, wherein cells were preplated into the flask and after 1 hour the supernatant was removed from the flask and re-plated into a fresh collagen-coated flask. The supernatant was removed and replated after 30-40% of the cells adhered to each flask. Page 29, lines 14-23 does not explicitly recite the limitation. Thus, one skilled in the art would not consider the broadening of the limitation to be supported in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1635

Claims 154, 157-161, 163, 166-170, 173-178, 180-183, 185, 217, 223-226, and 229 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 154, 163, 170, 178, and 217 recite the limitation "re-plating non-adherent cells from step (a)" in step (ii). There is insufficient antecedent basis for this limitation in the claim. There is no step (a) in these claims.

Claims 157-161, 166-169, 173-177, 180-183, 185, 223, 224, 225, 226, and 229 are rejected under 112 second paragraph because the claims are dependent from claims 154, 163, 170, 178, 217.

Claims 154, 163, 170, 178, and 217 recite the limitation "re-plating step (b)" in step (iii). There is insufficient antecedent basis for this limitation in the claim. There is no step (b) in these claims.

Claims 157-161, 166-169, 173-177, 180-183, 185, 223, 225, 226, and 229 are rejected under 112 second paragraph because the claims are dependent from claims 154, 163, 170, 178, and 217.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1635

Claims 107, 114, 216 and 218 are rejected under 35 U.S.C. 102(b) as being anticipated by Rando et al. (55, cited on a PTO-1449). Rando teaches a method of isolating myoblasts (skeletal muscle derived progenitor cells) using the same method steps as recited in instant claims 107 and 216. See pages 1277-1284. Rando teaches the limitation in instant claims 114 and 218 (page 1277).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1635

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 190, 193, 194, 196, 197, 199, 201, 204, 206, 209-210 remain and claims 227-228 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atala (US 5,667,778) taken with Law (US 6,261,832). Atala teaches a method of treating conditions, which require the reconstruction of an anatomical area selected from the group consisting of gastrointestinal tract and urinary tract comprising injecting into a patient at a site in the anatomical area a suspension of smooth muscle cells in a biodegradable polymer solution (columns 12-14). The suspension can be injected via syringe and needle directly into the site wherever a bulking agent is desired, i.e. soft tissue deformity (column 9). Atala further teaches the cells can be used to augment sphincter muscle tissue (columns 8-9). However, Atala does not specifically teach using skeletal muscle cells in the method.

However, at the time the invention was made, Law teaches a method of augmenting tissue or organ using myogenic cells (abstract and columns 6-7). Law teaches that myoblasts are the only cells capable of natural cell fusion (columns 1 and 10). Law Further teaches that myoblasts are efficient and safe (column 1). Law teaches that cells can be used to replenish wounds (column 2). Law teaches that myoblast are embryonic cells (column 5). Law teaches methods using myoblast for replenishing lost cells (column 7). Law teaches that myogenic cells can be selected from skeletal, smooth, or cardiac (column 7). Law teaches using the cells in cosmetic usage and skin (breast and facial) augmentation. The cells can be used to avoid implantation of silicone (column 12). Thus, use of myoblast transfer to boost muscle mass is a

Art Unit: 1635

natural solution (column 12). The cells taught by Law are embraced by the cells used in the instant claims because the cells are myoblasts.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Atala and Law, namely to use myogenic cells in the method of augmenting or bulking bladder or sphincter muscle tissue. One of ordinary skill in the art would have been motivated to use myogenic cells instead of smooth muscle cells in the method taught by Atala because Law teaches that myogenic cells are embryonic cells and are efficient and safe and that myogenic cells are the only cells capable of natural cell fusion. In addition, Law teaches that myogenic cells could be used in a much more natural way to replace silicone injections and the use of myogenic cells to boost muscle mass is a natural solution.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Atala and Law, namely to use myogenic cells in the method of ameliorating a cosmetic defect (wound) by augmenting or bulking smooth muscle tissue. One of ordinary skill in the art would have been motivated to use myogenic cells instead of smooth muscle cells in the method taught by Atala because Law teaches that myogenic cells are the only cells capable of natural cell fusion and the use of myogenic cells to boost muscle mass is a natural solution.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 4/15/05 have been fully considered but they are not persuasive.

Art Unit: 1635

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., skeletal muscles survived over long time periods and enhance the smooth muscle tissue or skin tissue, essentially without adverse problems such as inflammation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have been motivated to use skeletal muscle cells instead of smooth muscle cells in the method taught by Atala because Law teaches that myoblast are the only cells capable of natural cell fusion and that myogenic cells can be used in a method of augmenting muscle tissue. In addition, the cells used in the presently claimed invention embrace the myoblast taught by Law even though they could be from skeletal, smooth or cardiac muscle because the cells are embryonic cells.

In response to applicant's argument that Law only describes his contemplated invention as providing "compositions and methods for repairing degenerating cells and replenishing lost cells in patients with hereditary or degenerative disease, in particular those characterized by

Art Unit: 1635

muscle malfunction, degeneration and weakness”, the argument is not found persuasive because a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Law teaches a method of augmenting tissue or organ using myogenic cells (abstract and columns 6-7). Law teaches that myoblasts are the only cells capable of natural cell fusion (columns 1 and 10). Law Further teaches that myoblasts are efficient and safe (column 1). Law teaches that cells can be used to replenish wounds (column 2). Law teaches methods using myoblast for replenishing lost cells (column 7). Law teaches using the cells in cosmetic usage and skin (breast and facial) augmentation. The cells can be used to avoid implantation of silicone (column 12). Thus, use of myoblast transfer to boost muscle mass is a natural solution (column 12).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is the case here. Applicant argues that Law is silent regarding the augmentation or bulking of specific smooth muscle tissue type in the presently claimed invention. However, Atala teaches a method of bulking smooth muscle cell (e.g., gastrointestinal tract and urinary tract) and Law teaches that myoblast are the only cells that are capable of natural cell fusion and myoblast can be use to boost muscle mass.

In response to applicant's assertion that the combine teachings of Atala and Law and further view of the knowledge in the art do not provide a reasonable expectation of success that

Art Unit: 1635

skeletal muscle-derived progenitor cells could augment or bulk non-skeletal, applicant's assertion is not compelling because other than the assertion there is no evidence of record to support applicant's assertion. See MPEP § 2145. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Claims 190, 193-197, 199-201, 204-206, 209-211 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Atala taken with Law as applied to claims 190, 193, 194, 196, 197, 199, 201, 204, 206, 209-210 and 227-228 above, and further in view of Li (US 5,206,028). Atala and Law do not specifically teach using collagen sponge material as the carrier in the methods.

However, at the time the invention was made, Li teaches that collagen membranes having physical and biological properties, which make them extremely suitable and desirable for all types of medical use (abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Atala and Law in further view Li, namely to use a collagen sponge material in the method of augmenting or bulking muscle tissue. One of ordinary skill in the art would have been motivated to use collagen sponge material in the methods because Li teaches that collagen membranes are suitable and desirable for medical use because they maintain their overall bulk density.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1635

Applicant's arguments filed 4/15/05 have been fully considered but they are not persuasive. Applicant's arguments have already been addressed in the prior 103(a) rejection. In response to applicant's argument that Li does not compensate for the above deficiencies of the primary and secondary references, the argument is not found persuasive because the primary and secondary reference teach the claimed method and Li was only provided to show that using sponge material in the claimed would have been obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 107, 216, 219, and 221 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 260, 266, 267, 273, 274, and 280 of U.S. Patent No. 6,866,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims from '842 are directed to using the same method of isolating muscle derived progenitor cells (skeletal muscle derived myoblasts) and a method of augmenting or bulking muscle tissue in the bladder muscle

Art Unit: 1635

tissue (urethra muscle tissue) using muscle derived progenitor cells. The method of isolating an end population of muscle-derived progenitor cells in instant claims 107, 170, 216, 219 and 221 is recited in claims 266, 273, and 280 of '842. One of ordinary skill in the art would reasonably determine that the claims of the instant application and the claims of '842 are obvious variants of one another.

Applicant's arguments filed 3/17/05 have been fully considered but they are not persuasive. Applicant argues that the claims from '842 are patentably distinct from applicant's presently amended claims, which are drawn to methods in which isolated skeletal muscle derived progenitor cells are injected in several types of muscle tissue.

Applicant's argument is not found persuasive because other than asserting that the claims are patentably distinct, the applicant does not disclose how the instant claims are patentably distinct from the claims of '842. The double patenting remains for the reasons of record.

Claims 107, 216, 219, and 221 are directed to an invention not patentably distinct from claims 260, 266, 267, 173, 274, and 280 of commonly assigned US Patent 6,866,842. Specifically, for the reasons set forth under the obviousness type patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Patent, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the

Art Unit: 1635

assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

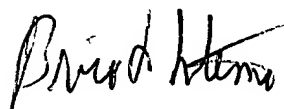
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Art Unit: 1635

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

A handwritten signature in black ink, appearing to read "Brian Whiteman", written in a cursive style.